

Practitioner's Docket No. 1581/128

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Petros Karouzakis et al.

Application No.: 09/762,602

Group No.: 1617

Filed: March 21, 2001

Examiner: Hui

For: Use of Misoprostol and/or Metabolites of Misoprostol for Treating Sexual Dysfunction in Women

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

ATTENTION: GROUP DIRECTOR

TRANSMITTAL OF SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT AFTER
MAILING DATE OF FINAL ACTION, NOTICE OF ALLOWANCE
OR ACTION THAT CLOSSES PROSECUTION BUT BEFORE
PAYMENT OF ISSUE FEE (37 C.F.R. § 1.97(d))

CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10*

*(When using Express Mail, the Express Mail label number is mandatory;
Express Mail certification is optional.)*

I hereby certify that, on the date shown below, this correspondence is being:

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37 C.F.R. § 1.8(a)

☒ with sufficient postage as first class mail.

37 C.F.R. § 1.10*

☐ as "Express Mail Post Office to Addressee"

Mailing Label No. _____ (mandatory)

TRANSMISSION

G facsimile transmitted to the Patent and Trademark Office, (703) _____ - _____

Signature

Date: December 15, 2003

Robert M. Asher

(type or print name of person certifying)

* Only the date of filing (' 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under ' 1.8 continues to be taken into account in determining timeliness. See ' 1.703(f). Consider "Express Mail Post Office to Addressee" (' 1.10) or facsimile transmission (' 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

**TIME OF TRANSMITTAL OF ACCOMPANYING
INFORMATION DISCLOSURE STATEMENT**

1. The information disclosure statement transmitted herewith is being filed *after* a final action under § 1.113, or a notice of allowance under § 1.311, whichever occurs first, but before, or simultaneously with, the payment of the issue fee.

STATEMENT AND FEE

2. In accordance with the requirements of 37 C.F.R. § 1.97(d):
 - A. Accompanying this transmittal is a statement, as specified in 37 C.F.R. § 1.97(e).
 - B. Applicant submits the fee set forth in § 1.17(p) (\$180.00).

FEE DUE

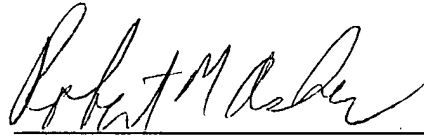
3. Fee due (§ 1.17(p)): \$180.00

METHOD OF PAYMENT OF FEE

4. Attached is a check in the amount of \$180.00.

A duplicate of this paper is attached.

Date: December 15, 2003



Robert M. Asher
Registration No. 30,445
Bromberg & Sunstein LLP
125 Summer Street, 11th Floor
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Practitioner's Docket No. 1581/128

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Petros Karouzakis et al.

Application No.: 09/762,602

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For: Use of Misoprostol and/or Metabolites of Misoprostol for Treating Sexual Dysfunction in Women

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATEMENT FOR SUPPLEMENTAL INFORMATION DISCLOSURE UNDER 37 C.F.R.
SECTION 1.97(e)

NOTE: A statement must state either: "(1) that each item of information contained in the information disclosure statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement, or (2) that no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in Section 1.56(c) more than three months prior to the filing of the information disclosure statement." 37 C.F.R. Section 1.97(e).

NOTE: "Section 1.97(e) makes it clear that a certification could contain either of two statements. One statement is that each item of information in an information disclosure statement was cited in a search report from a patent office outside the U.S. not more than three months prior to the filing date of the statement. Under this certification, it would not matter whether any individual with a duty actually knew about any of the information cited before receiving the search report. In the alternative, the certification could state that no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual having a duty to disclose more than three months prior to the filing of the statement." Notice of January 9, 1992, 1135 O.G. 13-25, at 13. (emphasis added). Thus: "If an item of information is submitted within three months of being cited in a communication from a foreign patent office in a counterpart foreign application, the certification can be properly made

CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. SECTION 1.8(a))

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☐ transmitted by facsimile to the Patent and Trademark Office, (703) ____-____.

Date: December 15, 2003

Signature

Robert M. Asher

(type or print name of person certifying)

regardless of any individual's previous knowledge of the information." *Id.*, 1135 O.G. at 19.

NOTE: "The certification can be based on present, good faith knowledge about when information became known without a search of files being made." Thus, for example, the certification of Section 1.97(e) does not preclude the use of the certification in an application by corporations whose practitioners have over the years reviewed thousands of patents and technical publications, even though they are unaware of the relevance of any one thereof to the application. Notice of January 9, 1992, 1135 O.G. 13-15, at 19.

NOTE: A copy of the foreign search report need not be submitted with the certification. Notice of April 20, 1992 (1138 O.G. 37-41, 40).

NOTE: "The phrase 'after making reasonable inquiry' makes it clear that the individual making the certification has a duty to make reasonable inquiry regarding the facts that are being certified. The certification can be made by a registered practitioner who represents a foreign client and who relies on statements made by the foreign client as to the date the information first became known. A registered practitioner who receives information from a client without being informed whether the information was known for more than three months, however, cannot make the certification without making reasonable inquiry. For example, if an inventor gave a publication to the attorney prosecuting an application with the intent that it be cited to the Office, the attorney should inquire as to when that inventor became aware of the publication and should not submit a certification under 37 C.F.R. 1.97(e)(2) to the Office until a satisfactory response is received. The certification can be based on present, good faith knowledge about when information became known without a search of files being made." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "Although it is recognized that an individual actually becomes aware of the information in the communication from a foreign patent office sometime after it was mailed, the mailing date of such a communication, if it occurs prior to a first awareness of the same information, would determine the date for filing of an information disclosure statement without a fee" in a certification procedure under Section 1.97(e). Notice of January 9, 1992, 1135 O.G. 13-25, at 19 (emphasis added).

NOTE: The mere absence of an item of information for a foreign patent office communication is not intended to represent an opportunity to delay the submission of a item known more than three months prior to the filing of an information disclosure statement to an individual having the duty of disclosure under Section 1.56. 62 Fed. Reg. 53,131, 53,150 (Oct. 10, 1997).

NOTE: "The certification under Section 1.97(e) should be made by a person who has knowledge of the facts being certified. The certification can be made by a practitioner who represents a foreign client and who relies on statements made by the foreign client as to the date the information first became known. A practitioner who receives information from a client without being informed whether the information was known for more than three months, however, cannot make the certification without making reasonable inquiry." Notice of January 9, 1992, 1135 O.G. 13-25 at 19.

NOTE: "The term counterpart foreign patent application means that a claim for priority has been made in either the U.S. application or a foreign application based on the other, or that the disclosures of the U.S. and foreign patent applications are substantively identical (e.g., an application filed in the European Patent Office claiming the same U.K. priority as claimed in the U.S. application)." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent or inventor." 37 C.F.R. Section 1.56(d) and

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) each inventor named in the application;

(2) each attorney or agent who prepares or prosecutes the application; and

(3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. Section 1.56(c).

**IDENTIFICATION OF INFORMATION DISCLOSURE STATEMENT
FOR WHICH THIS STATEMENT IS BEING MADE**

1. This statement is being made for the Information Disclosure Statement

☒ accompanying this statement.

☐ filed _____.

Date

STATEMENT

2. I, the person(s) signing below state:

☐ that each item of information contained in the information disclosure statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. 37 C.F.R. Section 1.97(e)(1).

NOTE: The three month period starts from the mailing date of the foreign patent office communication. Notice of January 9, 1992, 1135 O.G. 13-25 at 19. The mailing date is the "date on the communication by the foreign patent office." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

OR

☒ that no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and to the knowledge of the person signing the statement after making reasonable inquiry, was known to any individual designated in Section 1.56(c) more than three months prior to the filing of the information disclosure statement. 37 C.F.R. Section 1.97(e)(2).

NOTE: "The time at which information 'was known to any individual designated in 37 C.F.R. 1.56(c)' is the time when the information was discovered in association with the application even if awareness of the materiality came later." Notice of April 20, 1992 (1138 O.G. 37-41, 40).

IDENTIFICATION OF PERSON(S) MAKING THIS STATEMENT

3. The person making this statement is

(check each applicable item)

(a) ☐ the inventor(s) who signs below

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

(b) ☐ a person who is substantively involved in the preparation or prosecution of the application, and who is associated with the inventor, with the assignee, or with anyone to whom there is an obligation to assign the application (37 C.F.R. Section 1.56(c)) and who signs below.

SIGNATURE OF PERSON MAKING STATEMENT

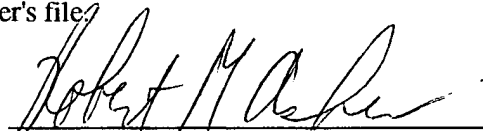
(type name of person who is signing)

Address of person who is signing

(c) ☒ the practitioner who signs below on the basis of the information:

(check each applicable item)

- ☐ supplied by the inventor(s).
☐ supplied by an individual designated in Section 1.56(c).
☒ in the practitioner's file.



SIGNATURE OF PRACTITIONER

Robert M. Asher

(type or print name of practitioner)

Bromberg & Sunstein LLP

125 Summer Street, 11th Floor

Boston, MA 02110-1618

Reg. No. 30,445

Tel. No. (617) 443-9292

Customer No.:002101



Practitioner's Docket No. 1581/128

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application

Inventor(s)

for

Title of invention

the specification of which is being transmitted herewith

OR

In re application of: Petros Karouzakis et al.

Application No.: 09/762,602

Group No.: 1617

Filed: March 21, 2001

Examiner: Hui

For: Use of Misoprostol and/or Metabolites of Misoprostol for Treating Sexual Dysfunction in Women

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

(Supplemental Information Disclosure Statement--page 1 of 7)

CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10*

(When using Express Mail, the Express Mail label number is *mandatory*;

Express Mail certification is *optional*.)

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37 C.F.R. SECTION 1.8(a)

37 C.F.R. SECTION 1.10*

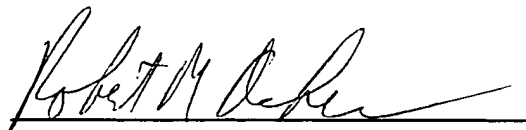
[x] with sufficient postage as first class mail.

☐ as "Express Mail Post Office to Addressee"

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TRANSMISSION

☐ transmitted by facsimile to the Patent and Trademark Office.


Signature

Date: December 15, 2003

Robert M. Asher

(type or print name of person certifying)

***WARNING:** Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. section 1.10(b).
"Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable C.F.R.e, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant:

- (1) Within three months of the filing date of a national application;
- (2) Within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or
- (3) Before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. section 1.97(b).

NOTE: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. section 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. section 1.56(c).

NOTE: The "duty as described in section 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by sections 1.97(b) - (d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13-25 at 17.

WARNING: "No information disclosure statement may be filed in a provisional application." 37 C.F.R. section 1.51(b).

List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: disC.F.R.d unused sections and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ Forms PTO/SB/08A and 08B (substitute for Form PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
 - 7A. ☐ JEPO Search Report
 - 7B. ☐ English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☐ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections _____, respectively, have been continued on ADDED PAGE(S).

NOTE :"Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

Section 1. Preliminary statements

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

SECTION 2. FORMS PTO/SB/08A and 08B (formerly Form PTO-1449)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Petros Karouzakis et al. Attorney Docket: 1581/128
 Serial No: 09/762,602 Art Group Unit: 1617
 Date Filed: March 21, 2001 Examiner Name: Hui
 Invention: Use of Misoprostol and/or Metabolites of Misoprostol for Treating Sexual Dysfunction in Women

LIST OF PATENTS AND PUBLICATIONS FOR
 APPLICANT'S INFORMATION DISCLOSURE STATEMENT

OTHER DOCUMENTS			
Examiner Initials	Ref. No.	Author	Title of Article, Title of Journal, Volume Number, Page Numbers, Date
	BB	Piletz, J. et al.	<i>Plasma MHPG Response to Yohimbine Treatment in Women With Hypoactive Sexual Desire</i> , Journal of Sex and Marital Therapy, Vol. 24, no. 1, p. 43-54, Jan-March 1998.
	BC	Ernst, E.; Pittler, E.H.	<i>Yohimbine For Erectile Dysfunction</i> , The Journal of Urology, February, 1998; 159 (2):433-436.
	BD	Kaplan, S. et al.	Abstract: <i>Safety and Efficacy of Sildenafil in Postmenopausal Women with Sexual Dysfunction</i> , Urology, vol. 53, issue 3, March, 1999, p. 481-488.
	BE		<i>Study: Viagra Ineffective for Female Sexual Dysfunction</i> , Canada Express RX, http://www.canadaexpressrx.com/viagrasotry29.html , March 8, 1999.
	BF		<i>Sexual Healing Probing the Problem of Sex Dysfunction in Women</i> , Boston, p. 79, June 2003.
	BG	Basson, R. et al.	<i>Efficacy and Safety of Sildenafil Citrate in Women with Sexual Dysfunction Associate with Female Sexual Arousal Disorder</i> , NCBI, http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=12150 , May, 2002.
	BH		<i>Sildenafil for Female Sexual Arousal Disorder</i> , National Horizon Scanning Centre, July 2002.
	BI		<i>Cialis and Levitra News, Viagra for Women</i> , http://www.buy-viagra-cialis-levitra.com/news/impotence/00000010.shtml , March 25, 2003.
	BJ		<i>Viagra and Women</i> , http://wowhub.com/ViagraAndWomen.htm .
	BK		<i>Does Viagra Work for Women? Researchers Say Yes!</i> , http://www.skifriends.com/does-viagra-work-for-women.htm , May 26, 2001.
	BL		<i>Bigger is Better When It Comes to the G Spot</i> , New Scientist.com, http://www.newscientist.com/news/news.jsp?id=99992495 , July 2, 2003.

Examiner Initials	Ref. No.	Author	Title of Article, Title of Journal, Volume Number, Page Numbers, Date
	BM	Jones, R.	<i>Orgasm 'G Spot' Documented in Women</i> , http://www.mercola.com/2002/jul20/orgasm.htm , July 20, 2002.
	BN	Finn, R.	<i>Sildenafil: Less SSRI-Related Sexual Dysfunction in Women?</i> , http://www.natural-hrt.com/artman/publish/article_135.shtml , March 13, 2003.
	BO	Goldhill, Jon	<i>Male and Female Sexual Dysfunction: Blockbuster Indication for Multiple Pharmacological Targets</i> , http://www.leaddiscovery.co.uk/target-discovery/abstracts/dossier-MDI002.html , September 6, 2002.
	BP	Jovanovic, L.	<i>Finally, It Is Our Turn!</i> , (Abstract), <i>Diabetes Care</i> , 25:787-788, January 31, 2002.
	BQ	Duncan L. et al.	<i>Sexual Dysfunction in Women. Do Antihypertensive Drugs Have an Impact?</i> , <i>Drug Safety</i> , March, 1993, 8 (3):225-34.
	BR	Smith	<i>Effects of Four Beta-Adrenergic Receptor Antagonists on Male Rat Sexual Behavior</i> , (Abstract), <i>Pharmacol Biochem Behavior</i> http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?CMD=Display&DB=PubMed , August 1990; 36 (4):713-7.

Examiner Signature: _____

Date Considered: _____

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation *if not* in conformance and not considered. Include copy of this form with next communication to applicant.

Section 6. Copies of Listed Information Items Accompanying This Statement

NOTE: 37 C.F.R. section 1.98(a)(2) requires that any information disclosure statement filed under section 1.97 shall include: "A legible copy of: (1) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed; and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included . . ."

NOTE: The wording in section 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.

Legible copies of all items listed in Forms PTO/SB/08A and 08B (substitute for Form PTO-1449) accompany this information statement.

(complete the following, if applicable)

☐ Exception(s) to above:

☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.

☐ Cumulative patents or publications identified in Section 5.

Section 10. Identification of Person(s) Making This Information Disclosure Statement

The person making this certification is

(check each applicable item)

- (a) ☐ the inventor(s) who signs below

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

- (b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. section 1.56(c))

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

- (c) ☒ the practitioner who signs below on the basis of the information:

(check each applicable item)

☐ supplied by the inventor(s).

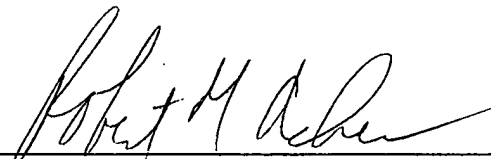
☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. section 1.56(c)).

☒ in the practitioner's file.

Reg. No.: 30,445

Tel. No.: (617) 443-9292

Customer No.: 002101



SIGNATURE OF PRACTITIONER

Robert M. Asher

(type or print name of practitioner)

Bromberg & Sunstein LLP

125 Summer Street, 11th Floor

P.O. Address

Boston, MA 02110